



## Complete Summary

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### **GUIDELINE TITLE**

Diagnosis and treatment of adult degenerative joint disease (DJD)/osteoarthritis (OA) of the knee.

### **BIBLIOGRAPHIC SOURCE(S)**

Institute for Clinical Systems Improvement (ICSI). Diagnosis and treatment of adult degenerative joint disease (DJD)/osteoarthritis (OA) of the knee. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2007 Mar. 41 p. [54 references]

### **GUIDELINE STATUS**

This is the current release of the guideline.

This guideline updates a previously released version: Diagnosis and treatment of adult degenerative joint disease (DJD) of the knee. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2004 Nov. 43 p.

### **\*\* REGULATORY ALERT \*\***

### **FDA WARNING/REGULATORY ALERT**

**Note from the National Guideline Clearinghouse:** This guideline references a drug(s) for which important revised regulatory information has been released.

- [June 15, 2005, COX-2 Selective \(includes Bextra, Celebrex, and Vioxx\) and Non-Selective Non-Steroidal Anti-Inflammatory Drugs \(NSAIDs\)](#): Labeling revised to include a boxed warning and a Medication Guide, highlighting the potential for increased risk of cardiovascular (CV) events and life-threatening gastrointestinal (GI) bleeding.
- [April 7, 2005, Bextra \(valdecoxib\), Cox-2 inhibitors, Celebrex \(celecoxib\), Non-steroidal anti-inflammatory drugs \(NSAIDS\) \(prescription and OTC, including ibuprofen and naproxen\)](#): Bextra (valdecoxib) withdrawn from the market and labels for other Cox-2 inhibitors and NSAIDS revised to include a boxed warning and a Medication Guide, highlighting the potential for increased risk of cardiovascular (CV) events and life-threatening gastrointestinal (GI) bleeding.

### **Additional Notice**

- [May 2, 2007, Antidepressant drugs](#): Update to the existing black box warning on the prescribing information on all antidepressant medications to include

warnings about the increased risks of suicidal thinking and behavior in young adults ages 18 to 24 years old during the first one to two months of treatment.

## COMPLETE SUMMARY CONTENT

**\*\* REGULATORY ALERT \*\***

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## SCOPE

### DISEASE/CONDITION(S)

Adult degenerative joint disease (DJD)/osteoarthritis of the knee

### GUIDELINE CATEGORY

Diagnosis

Evaluation

Treatment

### CLINICAL SPECIALTY

Family Practice

Internal Medicine

Orthopedic Surgery

Physical Medicine and Rehabilitation

Rheumatology

### INTENDED USERS

Advanced Practice Nurses

Allied Health Personnel

Health Plans

Hospitals

Managed Care Organizations

Nurses

Occupational Therapists

Physical Therapists

Physician Assistants  
Physicians

### **GUIDELINE OBJECTIVE(S)**

- To improve the efficacy of diagnostic imaging for evaluating degenerative joint disease (DJD)
- To increase the use of recommended conservative approach as first-line treatment for degenerative joint disease
- To increase patient education for patients with degenerative joint disease

### **TARGET POPULATION**

Established patients (one who has been seen at his or her primary clinic or medical group at least once) who complain of a painful knee that may be due to degenerative joint disease/osteoarthritis

### **INTERVENTIONS AND PRACTICES CONSIDERED**

#### **Triage**

1. Phone follow-up
2. Schedule provider visits according to urgency criteria
3. Provide patient with education on home self-care
4. Home self-care including rest, ice, compression, elevation, and analgesics (acetaminophen, ibuprofen, aspirin, and naproxen sodium )

#### **Diagnosis**

1. Differential diagnosis via history, physical examination, laboratory tests, x-rays, joint taps, magnetic resonance imaging, bone scan, computed tomography, and additional studies, as applicable
2. Laboratory testing including gram stain and bacterial culture, crystal analysis, cell count and differential, synovial fluid, and Lyme test, as applicable
3. Assessments for osteoarthritis as appropriate: iron studies; calcium; phosphorus, and alkaline phosphatase; features of acromegaly; serum and urine homogentisic acid; liver function tests; and diabetes testing
4. Referral to a specialist

#### **Treatment**

1. Patient education
2. Pain management with:
  - Joint protection (weight reduction, knee stress avoidance)
  - Physical modalities (cold, heat)
  - Medications (acetaminophen, nonsteroidal anti-inflammatory drugs, COX-2 inhibitors, glucosamine, chondroitin sulfate, and narcotics)
  - Miscellaneous pain relievers (electrical stimulation, massage, and acupuncture, wedge insoles, unloader braces, knee sleeves)
  - Cognitive restructuring, stress management, and relaxation
  - Education regarding basic sleep hygiene measures

3. Exercise including active range of motion, progressive walking, and quadriceps strengthening
4. Assistive devices including a splint, brace, cane, crutch or walker
5. Physical therapy
6. Follow-up including medication changes, injections (intra-articular corticosteroids such as triamcinolone, hyaluronan injection, exercise, and referral to specialty providers

## **MAJOR OUTCOMES CONSIDERED**

- Diagnosis of degenerative joint disease
- Pain and inflammation rates
- Range of motion
- Patient functioning and safety
- Adverse reactions to treatment

## **METHODOLOGY**

### **METHODS USED TO COLLECT/SELECT EVIDENCE**

Searches of Electronic Databases

### **DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE**

A literature search of clinical trials, meta-analysis, and systematic reviews is performed.

### **NUMBER OF SOURCE DOCUMENTS**

Not stated

### **METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE**

Weighting According to a Rating Scheme (Scheme Given)

### **RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE**

Key conclusions (as determined by the work group) are supported by a conclusion grading worksheet that summarizes the important studies pertaining to the conclusion. Individual studies are classed according to the system presented below, and are designated as positive, negative, or neutral to reflect the study quality.

#### **Conclusion Grades:**

**Grade I:** The evidence consists of results from studies of strong design for answering the question addressed. The results are both clinically important and consistent with minor exceptions at most. The results are free of any significant doubts about generalizability, bias, and flaws in research design. Studies with

negative results have sufficiently large samples to have adequate statistical power.

**Grade II:** The evidence consists of results from studies of strong design for answering the question addressed, but there is uncertainty attached to the conclusion because of inconsistencies among the results from the studies or because of minor doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from weaker designs for the question addressed, but the results have been confirmed in separate studies and are consistent with minor exceptions at most.

**Grade III:** The evidence consists of results from studies of strong design for answering the question addressed, but there is substantial uncertainty attached to the conclusion because of inconsistencies among the results of different studies or because of serious doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from a limited number of studies of weak design for answering the question addressed.

**Grade Not Assignable:** There is no evidence available that directly supports or refutes the conclusion.

### **Study Quality Designations**

The quality of the primary research reports and systematic reviews are designated in the following ways on the conclusion grading worksheets:

**Positive:** indicates that the report or review has clearly addressed issues of inclusion/exclusion, bias, generalizability, and data collection and analysis.

**Negative:** indicates that these issues (inclusion/exclusion, bias, generalizability, and data collection and analysis) have not been adequately addressed.

**Neutral:** indicates that the report or review is neither exceptionally strong nor exceptionally weak.

**Not Applicable:** indicates that the report is not a primary reference or a systematic review and therefore the quality has not been assessed.

### **Classes of Research Reports:**

#### **A. Primary Reports of New Data Collection:**

Class A:

- Randomized, controlled trial

Class B:

- Cohort study

Class C:

- Nonrandomized trial with concurrent or historical controls
- Case-control study
- Study of sensitivity and specificity of a diagnostic test
- Population-based descriptive study

Class D:

- Cross-sectional study
- Case series
- Case report

B. Reports that Synthesize or Reflect upon Collections of Primary Reports:

Class M:

- Meta-analysis
- Systematic review
- Decision analysis
- Cost-effectiveness analysis

Class R:

- Consensus statement
- Consensus report
- Narrative review

Class X:

- Medical opinion

## **METHODS USED TO ANALYZE THE EVIDENCE**

Review of Published Meta-Analyses  
Systematic Review with Evidence Tables

## **DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE**

Not stated

## **METHODS USED TO FORMULATE THE RECOMMENDATIONS**

Expert Consensus

## **DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS**

**New Guideline Development Process**

A new guideline, order set, and protocol is developed by a 6- to 12-member work group that includes physicians, nurses, pharmacists, other healthcare professionals relevant to the topic, along with an Institute for Clinical Systems Improvement (ICSI) staff facilitator. Ordinarily, one of the physicians will be the leader. Most work group members are recruited from ICSI member organizations, but if there is expertise not represented by ICSI members, 1 or 2 members may be recruited from medical groups or hospitals outside of ICSI.

The work group will meet for seven to eight three-hour meetings to develop the guideline. A literature search and review is performed and the work group members, under the coordination of the ICSI staff facilitator, develop the algorithm and write the annotations and footnotes and literature citations.

Once the final draft copy of the guideline is developed, the guideline goes to the ICSI members for critical review.

## **RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS**

Not applicable

## **COST ANALYSIS**

A formal cost analysis was not performed and published cost analyses were not reviewed.

## **METHOD OF GUIDELINE VALIDATION**

Clinical Validation-Pilot Testing  
Internal Peer Review

## **DESCRIPTION OF METHOD OF GUIDELINE VALIDATION**

### **Critical Review Process**

Every newly developed guideline or a guideline with significant change is sent to ICSI members for Critical Review. The purpose of critical review is to provide an opportunity for the clinicians in the member groups to review the science behind the recommendations and focus on the content of the guideline. Critical review also provides an opportunity for clinicians in each group to come to consensus on feedback they wish to give the work group and to consider changes necessary across systems in their organization to implement the guideline.

All member organizations are expected to respond to critical review guidelines. Critical review of guidelines is a criterion for continued membership within the Institute for Clinical Systems Improvement (ICSI).

After the critical review period, the guideline work group reconvenes to review the comments and make changes, as appropriate. The work group prepares a written response to all comments.

### **Approval**

Each guideline, order set, and protocol is approved by the appropriate steering committee. There is one steering committee each for Respiratory, Cardiovascular, OB/GYN, and Preventive Services. The Committee for Evidence-based Practice approves guidelines, order sets, and protocols not associated with a particular category. The steering committees review and approve each guideline based on the following:

- Member comments have been addressed reasonably.
- There is consensus among all ICSI member organizations on the content of the document.
- Within the knowledge of the reviewer, the scientific recommendations within the document are current.
- Either a critical review has been carried out, or to the extent of the knowledge of the reviewer, the changes proposed are sufficiently familiar and sufficiently agreed upon by the users that a new round of critical review is not needed.

Once the guideline, order set, or protocol has been approved, it is posted on the ICSI Web site and released to members for use. Guidelines, order sets, and protocols are reviewed regularly and revised, if warranted.

### **Revision Process of Existing Guidelines**

ICSI scientific documents are revised every 12 to 36 months as indicated by changes in clinical practice and literature. Every 6 months, ICSI checks with the work group to determine if there have been changes in the literature significant enough to cause the document to be revised earlier than scheduled.

Prior to the work group convening to revise the document, ICSI members are asked to review the document and submit comments. During revision, a literature search of clinical trials, meta-analysis, and systematic reviews is performed and reviewed by the work group. The work group will meet for 1-2 three-hour meetings to review the literature, respond to member organization comments, and revise the document as appropriate.

If there are changes or additions to the document that would be unfamiliar or unacceptable to member organizations, it is sent to members to review prior to going to the appropriate steering committee for approval.

### **Review and Comment Process**

ICSI members are asked to review and submit comments for every guideline, order set, and protocol prior to the work group convening to revise the document.

The purpose of the Review and Comment process is to provide an opportunity for the clinicians in the member groups to review the science behind the recommendations and focus on the content of the order set and protocol. Review and Comment also provides an opportunity for clinicians in each group to come to consensus on feedback they wish to give the work group and to consider changes needed across systems in their organization to implement the guideline.



All member organizations are encouraged to provide feedback on order sets and protocol, however responding to Review and Comment is not a criterion for continued membership within ICSI.

After the Review and Comment period, the work group reconvenes to review the comments and make changes as appropriate. The work group prepares a written response to all comments.

## RECOMMENDATIONS

### MAJOR RECOMMENDATIONS

**Note from the National Guideline Clearinghouse (NGC) and the Institute for Clinical Systems Improvement (ICSI):** In addition to updating their clinical guidance, ICSI has developed a new format for all guidelines. Key additions and changes include: combination of the annotation and discussion section; the addition of "Key Points" at the beginning of most annotations; the inclusion of references supporting the recommendations; and a complete list of references in the Supporting Evidence section of the guideline. For a description of what has changed since the previous version of this guidance, refer to "[Summary of Changes Report -- March 2007](#)."

The recommendations regarding adult degenerative joint disease (DJD)/osteoarthritis (OA) of the knee are presented in the form of algorithms with 13 components, accompanied by detailed annotations. Algorithms are provided for [Diagnosis and Treatment of Adult Degenerative Joint Disease/Osteoarthritis of the Knee - Triage](#) and [Diagnosis and Treatment of Adult Degenerative Joint Disease/Osteoarthritis of the Knee](#); clinical highlights and selected annotations (numbered to correspond with the algorithm) follow.

Class of evidence (A-D, M, R, X) and conclusion grade (I-III, Not Assignable) definitions are repeated at the end of the "Major Recommendations" field.

### Clinical Highlights

- Schedule a same day appointment if a patient reports the following: hot, swollen joint with or without fever and/or feeling ill, cannot bear weight on leg, leg or foot is cool or blue, deformity, severe pain, locked knee, and/or patient demands to be seen the same day. (*Annotation #1c*)
- For patients who are not scheduled for a same day visit, provide advice on basic techniques to reduce pain and inflammation in the knee. These include rest, ice, compression, elevation, and the use of appropriate over-the-counter analgesics. (*Annotation #1e*)
- When a patient is diagnosed with DJD of the knee, avoid obtaining an x-ray on the first visit unless specifically indicated. (*Annotation #6*)
- Educate the patient regarding overall goals of treatment. These include education regarding the disease and self-management, pain reduction, exercise that promotes joint health, and improvement in patient functioning and safety. Consider referral to physical therapy. (*Annotation #10*)

## **Diagnosis and Treatment of Adult Degenerative Joint Disease/Osteoarthritis of the Knee - Triage Algorithm Annotations**

### **1c. Does Patient Need to Be Seen Today?**

The time frame in which a patient may be seen can be determined by asking a series of triage questions. The questions are intended to determine which symptoms require more urgent treatment by a physician and which ones can be managed through phone advice.

Phone follow-up is one way to ensure that patients keep appointments. These follow-ups can provide additional slots for patient appointments for capitated products. They increase revenue generation for fee-for-service products. Some clinics, however, may not have the staff to support this activity.

The patient should receive an immediate urgent care, emergency department, clinic, provider visit if he or she meets any of the following criteria:

- Hot, swollen joint, with or without fever and/or feeling ill
  - This criterion captures the patient with a possibility of an acute bacterial joint or periarticular infection, either of which would require immediate attention.
- Cannot bear weight on leg
  - This criterion captures the patient with:
    - Atypical bacterial infection
    - Atraumatic fracture
    - Traumatic fracture or derangement
- Leg or foot is cool and/or blue
  - This criterion captures the patient with an acute vascular occlusive event.
- Deformity
  - This criterion captures the patient with a fracture.
- Severe pain
  - This criterion captures the patient with an acute vascular occlusive event.

Refer to the National Guideline Clearinghouse (NGC) summary of the Institute for Clinical Systems Improvement (ICSI) guideline [Venous Thromboembolism](#).

- Locked knee (unable to bend or extend)
  - This criterion suggests torn cartilage or a loose body.
- Patient demands to be seen today
  - This criterion captures the patient with other conditions for which immediate attention may be required.

If the patient meets any of the following criteria, a provider should review the triage decision and determine when the patient should be scheduled for a visit:

- Now taking chemotherapy for cancer

- This criterion requires review of the patient who may be on immunosuppressant medications (and who therefore may not demonstrate typical manifestations of infection).
- Now taking immunosuppressive drugs
  - This criterion requires review of the patient who may be on immunosuppressant medications (and who therefore may not demonstrate typical manifestations of infection).
- History of diabetes
  - This criterion requires review of the patient who may have poor sensation (diabetic neuropathy) and who therefore may not be able to accurately report symptoms of conditions which may require immediate attention.
- Sickle cell anemia
  - This criterion requires review of the patient who may have a sickle cell crisis or acute vascular occlusive event.
- On prednisone
  - This criterion requires review of the patient who may not demonstrate typical manifestations of infection.

#### **1d. Schedule Visit According to Urgency**

The patient should receive an appointment within the next three days if he or she meets any of the following criteria:

- Unable to go to work or school due to pain
  - The provider will need to appropriately assess disability status.
- Swelling
  - Swelling suggests conditions for which medical care positively affects morbidity (i.e., sprain, strain)

Patients with other types of knee pain should be scheduled for the next available routine visit.

#### **1e. Provide Appropriate Patient Education**

##### **Key Points:**

- Patient education should include advice on basic techniques such as rest, ice, compression, elevation and the use of appropriate over-the-counter analgesics.
- Recommending the use of over-the-counter analgesics or non-steroidal anti-inflammatory drugs (NSAIDs) prior to the first visit is controversial.

When a patient is scheduled for an appointment within three days or several weeks, recommendations for home self-care should be given by the medical information nurse or other appropriate personnel. This pre-appointment education does not take the place of a provider visit, but is only interim advice.

Education should include advice on basic techniques to reduce pain and inflammation in the affected joint. Such techniques include rest, ice, compression, elevation, and the use of appropriate over-the-counter analgesics as follows:

**Rest:** Reduce or avoid activities that aggravate the pain. Alternate work with rest throughout your day.

**Ice:** Ice pack applied to the affected joint for 10 to 15 minutes several times a day. Protect the skin with clothing or a towel.

**Compression:** If swelling is present, a compression such as Ace™ wrap dressing or sleeve may be used. It should be unwrapped and rewrapped three to four times per day.

**Elevation:** Elevate the affected extremity above the level of your heart to help reduce swelling.

**Analgesics:** Recommend acetaminophen in standard over-the-counter doses for pain if the patient has no signs of liver disease or excessive intake of alcohol. Over-the-counter anti-inflammatories (NSAIDs) such as ibuprofen, naproxen sodium, or acetylsalicylic acid may be used if the patient has no history of ulcer disease, diabetes, renal disease, liver disease, coronary artery disease, or bleeding diathesis; is not currently using anticoagulants such as warfarin or heparin, has no sensitivity to these medications, and is not pregnant. Caution should be exercised in recommending chronic NSAID use in persons over age 65 due to the high risk of gastrointestinal hemorrhage in this population over time.

The following over-the-counter medications may be recommended by the triage person at the clinic. These medications and dosages will provide analgesic and/or anti-inflammatory effects.

- Acetaminophen 500 mg extra strength tablets, one to two tablets up to four times per day, but do not exceed eight tablets per day
- Ibuprofen 200 mg tablets, one to two tablets every four to six hours as needed, up to six tablets per day
- Aspirin 325 mg one or two tablets every four hours as needed, not to exceed 4,000 mg/day
- Naproxen sodium 220 mg one to two tablets every 8 to 12 hours, up to three tablets in 24 hours; for those over age 65, one tablet every 12 hours, up to two tablets per 24 hours

These medications need to be taken on a full stomach and on an as-needed basis. Should a patient choose to take the highest dosage, he or she may achieve an anti-inflammatory effect from ibuprofen, aspirin, or naproxen sodium. Acetaminophen has only analgesic effects.

Since there is no data that one NSAID is more efficacious than another, the use of ibuprofen or naproxen sodium would be most cost effective. It is suggested that NSAID use should be prioritized on the basis of cost.

The College of Rheumatology recommends patients who have comorbidities and are taking chronic medication may require liver and renal functioning tests.

A patient education brochure or other written information to reinforce home self care instruction may be offered to the patient. This information may be given over

the phone, or the patient may be able to pick it up at the clinic if the clinic has the information available in a handout or brochure. Recommended patient education resources are listed in the Support for Implementation section of the original guideline document.

In certain systems, telephone follow-up may be used to confirm appointments or to allow patients to cancel appointments if home self-care has resolved the initial problem.

***Evidence supporting this recommendation is of classes: A, C, D***

## **Diagnosis and Treatment of Adult Degenerative Joint Disease/Osteoarthritis of the Knee Algorithm Annotations**

### **2. Provider Visit**

The provider visit should focus on diagnosis of degenerative joint disease/osteoarthritis of the knee rather than the differential diagnosis of knee pain.

#### **History**

- Age at first sign of painful symptoms. Have you had this pain before? Is it continuous or episodic?
- How did the pain present? (sudden onset or slow worsening over time)?
- How would you classify the pain? (sharp, dull, pinching, episodic, tight)?
- How would you rate your average pain over the last month (0-10)?
- What activity reproduces the pain? What makes it go away?
- Where is the pain?
- Are there any associated symptoms (locking, swelling, giving way, stiffness)?
- Activity history: What are you doing for exercise? What have you changed about your exercise regimen? What kind of work do you do?
- Previous treatments/surgery/diagnostic studies.
- Do you have any chronic medical illnesses? Any allergies?
- Ask differentiating questions (e.g., does patient have a history of blood clots, psoriasis, gout, liver disease, or a recent deer tick bite)?

#### **Physical Examination**

Typical physical examination findings in degenerative arthritis of the knee include:

- Swelling due to effusion with little synovial thickening, usually with little warmth
- Atrophy of the surrounding muscles
- Active and passive range of motion may both be restricted
- Crepitus
- Pain and muscle spasm at the extremes of existing range of motion

- Joint deformity

The physical examination may include some or all of the following components as appropriate:

- Inspection for deformity or abnormalities
- Check foot pulses
- Tenderness
- Presence and location of warmth or erythema
- Presence and location of swelling or effusion
- Range of motion, active and passive
- Assess stability, varus, valgus, posterior drawer, Lachman
- Meniscal compression (McMurray's test)
- Crepitance
- Assessment of patellar function
- Evaluation of gait

***Evidence supporting this recommendation is of class: D***

### **3. History and Physical Examination Indicate Degenerative Joint Disease/Osteoarthritis?**

A history and physical examination may produce a nonspecific result. The practitioner may wish to get laboratory tests, x-rays, or other tests to help diagnose the patient's condition. It is possible that a patient has both degenerative joint disease/osteoarthritis and another diagnosis.

In general, the following are consistent with the diagnosis of degenerative joint disease of the knee:

- Less than 30 minutes of morning stiffness
- Long-standing pain that increases with weight bearing or stairs and lessens with rest
- Insidious onset
- Bony deformity (osteophyte)
- Contracture
- Crepitation on movement
- Effusions which are not warm as in inflammatory arthritis

The following are inconsistent with degenerative joint disease of the knee:

- Fever or chills
- Erythema
- Warmth
- Large effusions
- Locking or giving way

***Evidence supporting this recommendation is of class: R***

### **6. Further Diagnostic Testing**

If history and physical examination are not conclusive for degenerative joint disease alone, further diagnostic testing is indicated. For the purposes of this guideline, diagnostic testing includes x-rays, joint taps, magnetic resonance imaging (MRI), bone scan, computed tomography (CT), and laboratory tests.

## **X-Rays**

With a diagnosis of degenerative joint disease of the knee, avoid obtaining an x-ray on the first visit unless it is specifically indicated. Indications for x-rays in the evaluation of joint pain may include:

- History of trauma to rule out fracture
- Presence of significant effusion – especially monarticular arthritis
- After physical examination, the pain cannot be explained by ligamentous strain or bursitis, and the patient has not had a prior x-ray of that joint done
- Loss of joint range of motion without an established pre-existing condition
- Severe joint pain – even with known pre-existing diagnosis at that joint
- Pre-referral to an orthopedist – if surgery is contemplated
- Persistent significant knee pain, especially in a young patient
- Conservative treatment failed

If the physician chooses to obtain an x-ray, standing anteroposterior (weight bearing), lateral (possibly weight bearing) and patellar (tangential) are recommended. Standing anteroposterior more reliably show joint space narrowing than other views. The American College of Radiology Appropriateness criteria was reviewed and supports an x-ray, knee anteroposterior standing or supine (ACR Appropriateness criteria).

When a diagnosis of degenerative joint disease of the knee is made, computed tomography, bone scans and magnetic resonance imaging are not recommended.

## **Indications for laboratory testing in degenerative joint disease**

- Nontraumatic monarticular effusions with swelling generally require aspiration with the following tests performed on the fluid (if the fluid is not straw colored and clear):
  - Gram stain and bacterial culture
  - Crystal analysis
  - Cell count and differential
  - Not recommended: glucose, protein

The synovial fluid in osteoarthritis should be noninflammatory (i.e., less than 200 white blood cells [wbc]/mm<sup>3</sup>), but in a flare could rise to 1,000-2,000 wbc/mm<sup>3</sup>. Fluid should be clear to only faintly turbid.

Consider a Lyme test in the presence of monarticular arthritis with joint swelling if the patient gives a history of deer tick bite, erythema chronicum migrans (ECM) rash or possible exposure to ticks.

- Consider referral or further evaluation for infection, inflammation, neoplastic or toxic etiologies. Lyme serology and synovial fluid analysis are suggested in inflammatory disease.
- If a patient has osteoarthritis by x-ray that is not due to past trauma or known process and if the patient is younger than 50, the following may be considered:
  - Iron studies (Fe/TIBC) - less than 75 percent saturation and/or ferritin greater than 300 to rule out hemochromatosis
  - Calcium, phosphorus and alkaline phosphatase to evaluate for hyperparathyroidism
  - Features of acromegaly: check phosphorus, glucose, consider plasma growth hormone level.
  - Dark urine on standing or black shards in synovial fluid: check serum and urine homogentisic acid
  - Abnormal liver function tests: consider Wilson's disease or hemochromatosis
  - Diabetes may accelerate the osteoarthritis process and elevated blood sugar should raise the question of hemochromatosis or acromegaly in the appropriate clinical setting
  - An elevated serum uric acid does not make a diagnosis of gout

***Evidence supporting this recommendation is of class: D, R***

## **7. Referral to Specialty Providers**

When specialty referral is indicated, coordinated management by the primary care provider and a musculoskeletal specialty provider is desirable. On the initial visit, the provider may reach a diagnosis that requires further evaluation or treatment by a specialty provider. Referral to rheumatologist, orthopedic surgeon, physical medicine and rehabilitation specialist, or another musculoskeletal specialist may be recommended for patients:

- With a systemic rheumatic disease such as rheumatoid arthritis, systemic lupus erythematosus, scleroderma, vasculitis, inflammatory myopathy, and severe osteoporosis
- With functional deterioration due to a rheumatic disease
- With septic arthritis or osteomyelitis
- With trauma such as a fracture or ligament injury that may require surgery or other treatment that the primary care physician is unable to provide
- With a primary or metastatic malignancy
- With a laboratory abnormality if uncertainty exists about its interpretation
- With chronic musculoskeletal problems who are responding poorly to treatment
- Whose function is impaired enough to significantly impact either vocational or avocational interests



- Who have fallen or are at risk of falling or who have other safety issues
- With a misalignment which might benefit from orthotics

A patient may not respond after standard therapy options. Consideration may then be given to referral to an arthritis specialist-rheumatologist, physical medicine and rehabilitation specialist, or orthopedic surgeon.

***Evidence supporting this recommendation is of class: R***

## **10. Treatment of Degenerative Joint Disease/Osteoarthritis of the Knee**

### **Key Points:**

- The overall goals of treatment are to:
  - Provide the patient with an understanding of the disease and self management
  - Reduce pain
  - Instruct in exercises to promote joint health
  - Improve overall patient functioning and safety
- Treatment should include the following components in a progressive fashion over time:
  - Patient education
  - Pain management
  - Exercise
  - Assistive devices
  - Physical therapy
- A follow-up visit should be scheduled three to six weeks after the initial visit

### **Patient Education**

Treatment at the initial visit begins with education. A discussion of the disease and its natural history will allow realistic goals for treatment to be established. The patient should be instructed in methods of proper body mechanics and joint protection. Lifestyle or environment changes should be suggested to eliminate excessive and recurrent trauma. Weight reduction should be recommended for overweight individuals. Moderate exercise should be encouraged. Vigorous activities that produce prolonged pain and inflammation should be avoided. A healthy, balanced diet with adequate vitamin intake is also recommended.

The provider may wish to consider a referral to education classes for self-management of arthritis. There are some computer-based education programs and several self-help books that may be appropriate. If the patient seems to need more help in problem solving to implement self-care, consider referral to a nurse for medication instruction, physical therapy for exercise instruction, or an occupational therapist for joint protection instruction.

Patient education should, in general, be reinforced with further written or verbal instruction.

Patient education resources describing joint protection, exercise, pain relief and basic healthy living habits are included in the Support for Implementation section of the original guideline document.

***Evidence supporting this recommendation is of class: C***

**Pain Management**

- Joint protection.

The patient should be instructed to avoid prolonged standing, kneeling, squatting, and stair climbing.

If obese, the patient should lose weight through modification of diet and a consistent low-impact aerobic conditioning program such as walking 30 to 60 minutes a day. If a patient with degenerative joint disease of the knee is unable to walk, consider referral to a physiatrist or physical therapist to assist in identifying appropriate alternative aerobic conditioning exercises.

If work or home activities seem to aggravate the problem, consider an outside evaluation by an appropriate health care professional.

- Physical modalities
  - Cold: ice packs, ice massage. These can be applied every three to four hours as needed for 15 to 20 minutes at a time.
  - Heat: warm bath or shower for 15 to 20 minutes, heat lamp, heating pad, warm compresses.
- Medications

The patient may be started on a course of acetaminophen or, if not effective, a nonsteroidal anti-inflammatory drug (NSAID) in appropriate analgesic doses if there are no contraindications to those medications. Since there is no proven efficacy of one NSAID over another, unless the patient has a history of peptic ulcer disease or is on anticoagulants, a less expensive one should be tried initially. A cyclooxygenase-2 (COX-2) inhibitor may be preferred for patients over age 65, those with a history of dyspepsia while taking COX-1-NSAIDs, or those with increased risk factors for gastrointestinal hemorrhage.

Elderly patients or those with increased blood pressure or risk factors for hypertension should be monitored for elevated blood pressure.

The nutraceutical agents glucosamine (1500 mg daily) and chondroitin sulfate (1200 mg daily) are widely available and tried by patients.

It is reasonable to recommend a 60 to 90 day trial of the combination of glucosamine and chondroitin sulfate, leaving the decision for ongoing (continuing) therapy to patients on an individual basis.

Narcotic medications are not advised as first-line treatment. Carefully monitored narcotic dosing may be considered for patients who are intolerant of NSAIDs and have not received sufficient benefit from physical therapy (PT), occupational therapy (OT) and other modalities. Dosing should begin in a progressive fashion. Systemic administration of adrenocorticosteroids is of no value. The American College of Rheumatology advocates the use of nonpharmacologic methods first and addition of medication only when additional analgesia is necessary.

Glucosamine should not be taken by those with allergy to shellfish. Other side effects may also occur.

- Miscellaneous pain relievers

When heat, cold, or medications are contraindicated or ineffective, the following may also be considered:

- Electrical stimulation such as transcutaneous electrical nerve stimulation (TENS)
- Massage
- Acupuncture
- Wedge insoles
- Unloader braces and knee sleeves
- Cognitive restructuring, stress management, relaxation

These are covered in pain management classes and support groups, the Arthritis Self-Help Course, and stress management classes. Consider referral to one of these classes if they are available.

- Ensure adequate restorative sleep

Provide instruction in basic sleep hygiene measures. Assess causes of nonrestorative sleep (pain, nocturia, depression, psychosocial stress, poor sleep hygiene, sleep disorder, congestive heart failure [CHF], etc.) and treat appropriately (relaxation before bed, instruct in use of sleep hygiene, amitriptyline, etc.)

***Evidence supporting this recommendation is of classes: A, B, C, D, M, R***

## **Exercise**

Exercise should be recommended for patients with degenerative joint disease of the knee. *[Conclusion Grade I: See Conclusion Grading A – Annotation #10 (Exercise Recommended) in the original guideline document]*

Exercise should include the following:

- Active range of motion for the hip, knee and ankle for maintaining and regaining range of motion and for promoting joint health and nutrition.

- Progressive walking. Begin walking for a duration that is well tolerated as a baseline such that it does not produce accelerating knee pain over successive days. Gradually increase the walk duration to a goal of 30–60 minutes five to seven days per week for closed chain strengthening and endurance training of the legs and for management of obesity. It may also contribute to a sense of well-being and pain control. Patients with limited tolerance for walking may prefer to start by walking in a pool, pushing a shopping cart, using an exercise bike, or other exercise equipment. Many patients do not have access to a pool or exercise equipment, however.
- Quad sets with vastus medialis obliquus activation at 15 degrees flexion to full knee extension in external hip rotation.

If the patient has difficulty walking, has contractures, has severe exercise intolerance, has fallen, or has other reasons for being unable to carry out this exercise program, consider referral to a physiatrist or physical therapist for a supervised program 2 or 3 times a week until the patient can perform an independent exercise program. A physical therapist may focus on the use of other modalities and more specific exercises to regain range of motion, strengthen the lower extremities, and improve endurance. If there is severe loss of function, a physiatrist may be helpful in supervising treatment for complex loss of function.

***Evidence supporting this recommendation is of classes: A, M***

### **Assistive Devices**

In some cases an assistive device such as a splint, brace, cane, crutch or walker may be an appropriate component of initial treatment.

Although anyone with appropriate training may instruct in the use of assistive devices, it may be most efficient to refer to a physical therapist, occupational therapist, ergonomist, or other professional who is trained to select and instruct in the use of these devices. A physical therapist can teach most patients to use a knee sleeve, cane or walker in one to two visits. Other assistive devices such as reachers, bath benches, raised toilet seats, grab bars, etc. may be suggested by an occupational therapist, sometimes in a visit to the home, where other safety issues may also be addressed. In the workplace, an occupational therapist, physical therapist, or ergonomist may suggest modifications. Sport-specific trainers may provide the best advice regarding athletic activities.

***Evidence supporting this recommendation is of class: R***

### **Physical Therapy**

Some patients may benefit from a supervised exercise program or from specific therapeutic modalities the therapist can provide.

## **11. Follow-Up Provider Visits**

The response to initial treatment should be assessed at follow-up visits. If the patient is responding well to initial treatment, key points of the treatment plan should be reviewed and reinforced and the following pain rating question should be repeated: How would you rate your average pain over the past month (0-10)? If the patient has had little improvement in symptoms or function or has had complications, the provider may consider progressive and/or escalated use of the approaches in Annotation #10, "Treatment of Degenerative Joint Disease/Osteoarthritis of the Knee."

### **Medication Change because of Lack of Effectiveness**

- Trial of a different anti-inflammatory medication. (Patient should be kept on medication for two to four weeks before trying a different one.)
- Injections
  - Local intra-articular corticosteroid injections may provide short-term or long-term relief of pain and may be appropriate at this point for some patients. A suggested dose is 40 mg triamcinolone.
  - A series of injections of hyaluronan preparation may also be appropriate to relieve pain at this point in some patients.

While corticosteroids require a single injection, hyaluronan is given in a series of injections - generally three to five.

Synthetic hyaluronates may be effective treatment for pain in selected patients with mild to moderate degenerative joint disease of the knee. *[Conclusion Grade II: See Conclusion Grading Worksheet B - Annotation #11 (Synthetic Hyaluronates), in the original guideline document.]*

### **Exercise**

The issue of exercise should be readdressed comprehensively at this time. Exercise may include a plan given through instruction at the clinic or a program supervised by a physical therapist, athletic trainer, or other comparable professional.

### **Referral to Specialty Providers**

A patient may not respond after standard therapy options. Consideration may then be given to referral to an arthritis specialist - Rheumatology, Physical Medicine and Rehabilitation, or Orthopedic Surgery. (See Annotation #7, "Referral to Specialty Providers.")

***Evidence supporting this recommendation is of classes. A, D, M***

### **Definitions:**

### **Conclusion Grades:**

**Grade I:** The evidence consists of results from studies of strong design for answering the question addressed. The results are both clinically important and consistent with minor exceptions at most. The results are free of any significant doubts about generalizability, bias, and flaws in research design. Studies with negative results have sufficiently large samples to have adequate statistical power.

**Grade II:** The evidence consists of results from studies of strong design for answering the question addressed, but there is uncertainty attached to the conclusion because of inconsistencies among the results from the studies or because of minor doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from weaker designs for the question addressed, but the results have been confirmed in separate studies and are consistent with minor exceptions at most.

**Grade III:** The evidence consists of results from studies of strong design for answering the question addressed, but there is substantial uncertainty attached to the conclusion because of inconsistencies among the results of different studies or because of serious doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from a limited number of studies of weak design for answering the question addressed.

**Grade Not Assignable:** There is no evidence available that directly supports or refutes the conclusion.

#### **Classes of Research Reports:**

##### **A. Primary Reports of New Data Collection:**

###### **Class A:**

- Randomized, controlled trial

###### **Class B:**

- Cohort study

###### **Class C:**

- Nonrandomized trial with concurrent or historical controls
- Case-control study
- Study of sensitivity and specificity of a diagnostic test
- Population-based descriptive study

###### **Class D:**

- Cross-sectional study
- Case series
- Case report

## B. Reports that Synthesize or Reflect upon Collections of Primary Reports:

### Class M:

- Meta-analysis
- Systematic review
- Decision analysis
- Cost-effectiveness analysis

### Class R:

- Consensus statement
- Consensus report
- Narrative review

### Class X:

- Medical opinion

## CLINICAL ALGORITHM(S)

Detailed and annotated clinical algorithms are provided for:

- [Diagnosis and Treatment of Adult Degenerative Joint Disease/Osteoarthritis of the Knee - Triage](#)
- [Diagnosis and Treatment of Adult Degenerative Joint Disease/Osteoarthritis of the Knee](#)

## EVIDENCE SUPPORTING THE RECOMMENDATIONS

### TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is classified for selected recommendations (see "Major Recommendations").

In addition, key conclusions contained in the Work Group's algorithm are supported by a grading worksheet that summarizes the important studies pertaining to the conclusion. The type and quality of the evidence supporting these key recommendations (i.e., choice among alternative therapeutic approaches) is graded for each study.

## BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

### POTENTIAL BENEFITS

Appropriate diagnosis and treatment of patients with degenerative joint disease/osteoarthritis of the knee

### POTENTIAL HARMS

- Concerns have been raised about the effects of the chronic use of acetaminophen on renal function and hepatic function (particularly in patients who consume alcohol).
- Analgesics or nonsteroidal anti-inflammatory drugs may change the patient's ability to sleep, work, perform household activities and adult daily living skills as a result of the use of the medication. Equally important are adverse effects such as drowsiness, gastrointestinal upset (or bleeding), and fluid retention.
- Heat and/or ice: These modalities have risks most commonly including neurovascular compromise, frostbite, and burns. Although rare, frostbite and burns can occur, and are occasionally severe, so patients should be advised to avoid these complications. Warm baths or showers can produce significant vasodilatation; therefore, the patient should be cautioned about orthostatic symptoms.
- Glucosamine should not be taken by those with allergy to shellfish. Other side effects may also occur.

### **Subgroups Most Likely to be Harmed**

- Over-the-counter analgesics or nonsteroidal anti-inflammatory drugs have possible side effects in the elderly including gastrointestinal bleeding, renal toxic effects, and central nervous system effects.
- Caution is urged in the chronic use of acetaminophen in patients who consume alcohol.

## **CONTRAINDICATIONS**

### **CONTRAINDICATIONS**

- Nonsteroidal anti-inflammatory drugs are contraindicated in patients on anticoagulants or with a bleeding diathesis.
- Warm baths and showers (15-20 minutes at 100-105 degrees F) may be contraindicated in patients with cardiovascular disease because of the possibility of orthostatic symptoms.
- Ice packs and ice massage are contraindicated in patients at risk of vasospasm or ischemia.

## **QUALIFYING STATEMENTS**

### **QUALIFYING STATEMENTS**

- These clinical guidelines are designed to assist clinicians by providing an analytical framework for the evaluation and treatment of patients, and are not intended either to replace a clinician's judgment or to establish a protocol for all patients with a particular condition. A guideline will rarely establish the only approach to a problem.
- This clinical guideline should not be construed as medical advice or medical opinion related to any specific facts or circumstances. Patients are urged to consult a health care professional regarding their own situation and any specific medical questions they may have.



## IMPLEMENTATION OF THE GUIDELINE

### DESCRIPTION OF IMPLEMENTATION STRATEGY

Once a guideline is approved for general implementation, a medical group can choose to concentrate on the implementation of that guideline. An action group is formed when a topic is selected as an initiative. In addition to the action group goals and measures, each medical group sets specific goals they plan to achieve in improving patient care based on the particular guideline(s). Each medical group shares its experiences and supporting measurement results within the action group. This sharing facilitates a collaborative learning environment. Action group learnings are also documented and shared with interested medical groups within the collaborative.

Currently, action groups may focus on one guideline or a set of guidelines such as hypertension, lipid treatment and tobacco cessation.

Detailed measurement strategies are presented in the original guideline document to help close the gap between clinical practice and the guideline recommendations. Summaries of the measures are provided in the National Quality Measures Clearinghouse (NQMC).

### Key Implementation Recommendations

The following system changes were identified by the guideline work group as key strategies for health care systems to incorporate in support of the implementation of this guideline.

1. Have a system in place that assures the patient will be seen for a same day appointment if a patient reports the following: hot, swollen joint with or without fever and/or feeling ill, cannot bear weight on leg, leg or foot is cool or blue, deformity, severe pain, locked knee, and/or patient demands to be seen the same day.
2. Develop a process that identifies a designated care provider who can provide advice on basic techniques to reduce pain and inflammation (e.g., ice, rest, compression) in the knee.
3. Have a system in place that guarantees that education will occur and/or educational materials are provided to the patient regarding overall goals of treatment. Education can include information regarding the disease and self-management, pain reduction, exercise that promotes joint health, and improvement in patient functioning and safety.
4. Develop a system that has pre-identified referral sources so as to remove barriers that will interfere with referrals to specialists.

### IMPLEMENTATION TOOLS

Clinical Algorithm  
Pocket Guide/Reference Cards  
Quality Measures

For information about [availability](#), see the "Availability of Companion Documents" and "Patient Resources" fields below.

## RELATED NQMC MEASURES

- [Diagnosis and treatment of adult degenerative joint disease \(DJD\)/Osteoarthritis \(OA\) of the knee: percentage of patients diagnosed with DJD with knee x-ray panels that include a standing view of the knee.](#)
- [Diagnosis and treatment of adult degenerative joint disease \(DJD\)/Osteoarthritis \(OA\) of the knee: percentage of patients with DJD with documented education in four comprehensive areas: protecting the joint, exercise, pain relief, healthy living habits.](#)

## INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

### IOM CARE NEED

Living with Illness

### IOM DOMAIN

Effectiveness  
Patient-centeredness

## IDENTIFYING INFORMATION AND AVAILABILITY

### BIBLIOGRAPHIC SOURCE(S)

Institute for Clinical Systems Improvement (ICSI). Diagnosis and treatment of adult degenerative joint disease (DJD)/osteoarthritis (OA) of the knee. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2007 Mar. 41 p. [54 references]

### ADAPTATION

Not applicable: The guideline was not adapted from another source.

### DATE RELEASED

1996 Jun (revised 2007 Mar)

### GUIDELINE DEVELOPER(S)

Institute for Clinical Systems Improvement - Private Nonprofit Organization

### GUIDELINE DEVELOPER COMMENT

Organizations participating in the Institute for Clinical Systems Improvement (ICSI): Affiliated Community Medical Centers, Allina Medical Clinic, Altru Health

System, Aspen Medical Group, Avera Health, CentraCare, Columbia Park Medical Group, Community-University Health Care Center, Dakota Clinic, ENT Specialty Care, Fairview Health Services, Family HealthServices Minnesota, Family Practice Medical Center, Gateway Family Health Clinic, Gillette Children's Specialty Healthcare, Grand Itasca Clinic and Hospital, HealthEast Care System, HealthPartners Central Minnesota Clinics, HealthPartners Medical Group and Clinics, Hutchinson Area Health Care, Hutchinson Medical Center, Lakeview Clinic, Mayo Clinic, Mercy Hospital and Health Care Center, MeritCare, Mille Lacs Health System, Minnesota Gastroenterology, Montevideo Clinic, North Clinic, North Memorial Care System, North Suburban Family Physicians, Northwest Family Physicians, Olmsted Medical Center, Park Nicollet Health Services, Pilot City Health Center, Quello Clinic, Ridgeview Medical Center, River Falls Medical Clinic, Saint Mary's/Duluth Clinic Health System, St. Paul Heart Clinic, Sioux Valley Hospitals and Health System, Southside Community Health Services, Stillwater Medical Group, SuperiorHealth Medical Group, University of Minnesota Physicians, Winona Clinic, Ltd., Winona Health

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## **GUIDELINE COMMITTEE**

Committee on Evidence-Based Medicine

## **COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE**

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## **FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST**

In the interest of full disclosure, ICSI has adopted a policy of revealing relationships work group members have with companies that sell products or services that are relevant to this guideline topic. The reader should not assume

that these financial interests will have an adverse impact on the content of the guideline. Readers of the guideline may assume that only work group members listed below have potential conflict of interest to disclose.

Alan Hunt, MD has received consulting or speaker fees in the past 12 months from Arthrex.

No other work group members have potential conflicts of interest to disclose.

ICSI's conflict of interest policy and procedures are available for review on ICSI's website at [www.icsi.org](http://www.icsi.org).

## **GUIDELINE STATUS**

This is the current release of the guideline.

This guideline updates a previously released version: Diagnosis and treatment of adult degenerative joint disease (DJD) of the knee. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2004 Nov. 43 p.

## **GUIDELINE AVAILABILITY**

Electronic copies: Available from the [Institute for Clinical Systems Improvement \(ICSI\) Web site](http://www.icsi.org).

Print copies: Available from ICSI, 8009 34th Avenue South, Suite 1200, Bloomington, MN 55425; telephone, (952) 814-7060; fax, (952) 858-9675; Web site: [www.icsi.org](http://www.icsi.org); e-mail: [icsi.info@icsi.org](mailto:icsi.info@icsi.org).

## **AVAILABILITY OF COMPANION DOCUMENTS**

The following are available:

- Diagnosis and treatment of adult degenerative joint disease (DJD)/osteoarthritis (OA) of the knee. Executive summary. Bloomington (MN): Institute for Clinical Systems Improvement, 2007 Mar. 1 p. Electronic copies: Available from the Institute [for Clinical Systems Improvement \(ICSI\) Web site](http://www.icsi.org).
- ICSI pocket guidelines. April 2006 edition. Bloomington (MN): Institute for Clinical Systems Improvement, 2006. 298 p.

Print copies: Available from ICSI, 8009 34th Avenue South, Suite 1200, Bloomington, MN 55425; telephone, (952) 814-7060; fax, (952) 858-9675; Web site: [www.icsi.org](http://www.icsi.org); e-mail: [icsi.info@icsi.org](mailto:icsi.info@icsi.org).

## **PATIENT RESOURCES**

None available

## **NGC STATUS**

This summary was completed by ECRI on December 4, 2002. The information was verified by the guideline developer on December 24, 2002. This summary was updated by ECRI on July 20, 2004 and January 12, 2005. This summary was updated on April 15, 2005 following the withdrawal of Bextra (valdecoxib) from the market and the release of heightened warnings for Celebrex (celecoxib) and other nonselective nonsteroidal anti-inflammatory drugs (NSAIDs). This summary was updated by ECRI on June 16, 2005, following the U.S. Food and Drug Administration advisory on COX-2 selective and non-selective non-steroidal anti-inflammatory drugs (NSAIDs). This NGC summary was updated by ECRI Institute on September 14, 2007. This summary was updated by ECRI Institute on November 9, 2007, following the U.S. Food and Drug Administration advisory on Antidepressant drugs.

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